भारतीय मानक
Indian Standard

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चिकित्सीय वस्त्रादि — बुनें हुये विस्कोस प्राथमिक मरहम पट्टियां — विशिष्टि

Medical Textiles — Knitted Viscose Primary Dressings — Specification

ICS 11.040.30; 59.080.01

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भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, 9 बहादुरशाह ज़फर मार्ग, नई दिल्ली-110002
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI-110002
www.bis.org.in www.standardsbis.in

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Technical Textiles for Medtech Applications Sectional Committee, TXD 36

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textile Division Council.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

MEDICAL TEXTILES — KNITTED VISCOSE PRIMARY DRESSINGS — SPECIFICATION

1 SCOPE

This standard specifies the requirements of uncoated knitted viscose primary dressings intended for medical use.

2 REFERENCES

The standards listed in Annex A contain provisions, which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated in Annex A.

3 TERMINOLOGY

For the purpose of this standard, the following term shall apply.

3.1 Knitted Viscose Primary Dressings – It consists of a warp knitted fabric manufactured from viscose multifilament yarn, with a nominal count of 22 tex.

4 WORKMANSIP AND FINISH

4.1 The dressing shall be clean and free from substances liable to cause tendering during storage. The product shall be free from toxic or harmful substances.

4.2 The manufacture and preparation of the dressings shall be conducted under proper hygienic conditions.

5 REQUIREMENTS

The knitted viscose primary dressings shall conform to the requirements specified in Table 1.

6 MARKING

6.1 Each pack of the knitted viscose primary dressings shall be legibly marked with the following information:

a) Name of the product;
b) Manufacturer's name, initials or trade-mark, if any;
c) Month and year of manufacture;
d) Dimensions; and
e) Any other statutory requirement as required by the law in force

Table 1 Requirements for Knitted Viscose Primary Dressings
(*Clause* 5)

Sl No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Identification of fibres	Complies	IS 667
ii)	Courses per dm, *Min*	76	Visual
iii)	Wales per dm, *Min*	80	Visual
iv)	Mass per square meter, g/m^2, *Min*	150	IS 1964
v)	Water soluble substances, percent, *Max*	2.5	IS 14944
vi)	Ether soluble substances, percent, *Max*	3.5	IS 14944
vii)	Sulphated ash, percent, *Max*	0.45	IS 14944
viii)	Loss on drying, percent, *Max* when dried to constant weight at 100 °C	14.0	–
ix)	Sterility	Complies	IS 10150

6.2 BIS Certification Marking

The product may also be marked with the Standard Mark.

6.2.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act*, 1986 and the Rules and Regulations made thereunder. The details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

7 SAMPLING AND CRITERIA FOR CONFORMITY

7.1 LOT

All the knitted viscose primary dressings of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot.

7.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

7.1.2 The number of dressings to be selected from the lot shall depend on the size of the lot and shall be in accordance with col 2, col 3 and col 5 of Table 2.

7.1.3 These dressings shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

Table 2 Number of Dressings to be Selected
(*Clause* 7.1.2)

Sl No.	Lot Size	Non-Destructive Testing		Destructive Testing	
		No. of Dressings to be Selected	Acceptance Number	No. of Dressings to be Selected	Acceptance Number
	N	*n*	*a*	n_1	a_1
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 280	13[1)]	1	8	0
ii)	281 - 500	20	2	8	0
iii)	501 - 1 200	32	3	13	0
iv)	1 201 - 3 200	50	5	13	0
v)	3 201 - 10 000	80	7	20	1

[1)] Or lot size when less than 13.

7.2 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

7.2.1 All dressings selected as per col 3 of Table 2 shall be examined for workmanship and finish (*see* **4.1**).

7.2.1.1 Any dressing failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in col 4 of Table 2. Otherwise, the lot shall be rejected.

7.2.2 Out of the sample already found satisfactory according to **7.2.1.1**, a sub-sample as per col 5 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

7.2.3 The lot shall be considered as conforming to the requirements of the specification, if the total number of defective dressings found in the sample (as per **7.2.2**) is less than or equal to the acceptance number as given in col 6 of Table 2.

8 PACKING

The knitted viscose primary dressings shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed to between the buyer and the seller. Packaging of the product should be such as to maintain the integrity of the product throughout its shelf life.

ANNEX A

(*Clause* 2.1)

LIST OF REFERRED INDIAN STANDARDS

IS No.	*Title*
667 : 1981	Methods for identification of textile fibres (*first revision*)
1964 : 2001	Method for determination of mass per unit length and mass per unit area of fabrics (*second revision*)
4905 : 1968	Methods for random sampling
10150 : 1981	Guide for sterilization of medical products
14944 : 2001	Surgical dressings – Methods of test

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Amendments Issued Since Publication

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BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones : 2323 0131, 2323 3375, 2323 9402 *Website*: www.bis.org.in

Regional Offices:			*Telephones*
Central	:	Manak Bhavan, 9 Bahadur Shah Zafar Marg NEW DELHI 110002	2323 7617 2323 3841
Eastern	:	1/14 C.I.T. Scheme VII M, V. I. P. Road, Kankurgachi KOLKATA 700054	2337 8499, 2337 8561 2337 8626, 2337 9120
Northern	:	SCO 335-336, Sector 34-A, CHANDIGARH 160022	260 3843 260 9285
Southern	:	C.I.T. Campus, IV Cross Road, CHENNAI 600113	2254 1216, 2254 1442 2254 2519, 2254 2315
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